

REMARKS

A. Amendment

Support for amended Claim 44 may be found in canceled Claim 45.

Support for Claim 46 may be found in Figure 2B.

Support for amended Claim 49 and new Claim 59 may be found in original Claims 2 and

3.

B. §112, 2nd Paragraph Rejection

Claims 44-56 and 58 are rejected under 35 U.S.C. 112, 2nd paragraph, as indefinite.

Claim 44 and dependent Claims 45-55 are indefinite because the food additive is defined as a singular cocoa polyphenol, whereas the dependent claims define the food additive as a mixture of cocoa polyphenols. In view of the amendment of the claim to recite "cocoa polyphenols" and to define specific cocoa polyphenols in the mixture, the rejection is overcome.

The Examiner considers Claim 46 indefinite because it is not clear if the phrase "wherein the procyanidin oligomers include dimers through dodecamers" means that the cocoa polyphenols comprise all of these oligomers or just include some of them. In view of the amendment of the claim to change "include" to "are selected from the group consisting of", it is believed this rejection is overcome.

Claim 49 is rejected because it omits the essential step of defatting the cocoa powder prior to extracting the cocoa polyphenols from the defatted cocoa powder. In view of the amendment of the claim to add the step of "defatting the cocoa powder," this rejection is overcome.

Claims 47-55 are rejected as indefinite because of their incorrect dependencies – i.e., Claim 49 depends from Claim 51, Claim 51 depends from Claim 49, and the rest of the claims

depend directly or indirectly from Claims 49 or 51. In view of the Amendment of Claim 49 to depend on Claim 44, not Claim 51, it is believed the rejection is overcome.

Claims 47, 49, and 54 are rejected because there is insufficient antecedent basis for the limitation "the cocoa extract" in line 1. In view of amendment of Claims 47 and 49 to depend on Claim 44, there is now an antecedent basis for "the cocoa extract" which is specifically referred to in Claim 44.

Claim 48 is rejected because there was insufficient antecedent basis for the limitation "certain cocoa procyanidin fractions" in line 1. In view of the amendment of the claim to depend from Claim 47, not Claim 50, there is now an antecedent basis in Claim 47 for "cocoa procyanidin fractions."

Claims 56 and 58 are rejected as incomplete for omitting essential elements. In view of the cancellation of the claims, the rejections are moot.

C. Obviousness-Type Double Patenting Rejection over U.S. 5,554,645

Claims 44-56 and 58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3 and 13 of U.S. Patent No. 5,554,645.

Although the conflicting claims are not identical, the Examiner believes that they are not patentably distinct from each other because the present claims are drawn to a food composition comprising a cocoa polyphenol as a food additive, whereas Claim 13 of US '645 is drawn to an antioxidant or preservative composition consisting essentially of a cocoa extract (containing cocoa polyphenols therein) which is prepared by the process of Claims 1-3 of the '645 patent. The Examiner believes it would have been obvious to one of ordinary skill in the art at the time

the claimed invention was made to add the claimed cocoa extract preservative of the '645 patent to a foodstuff to preserve it.

D. Applicants' Response to Obviousness-Type Double Patenting Rejection Over The '645 Patent

It is respectfully pointed out that claims directed to foods containing a cocoa extract comprising catechin, epicatechin, and procyanidin oligomers thereof are not obvious variants of claims directed to a preservative composition which consists essentially of polyphenols of oligomers 3 through 12. Please note the cocoa extract used as the food additive comprises catechin, epicatechin, and oligomeric procyanidins, whereas the cocoa extract preservative consists essentially of oligomers 3 through 12. Thus, the composition of the extract is different.

It is respectfully pointed out that neither the cocoa extract of the '875 patent or of this application are required to be prepared by the process described and claimed in the '875 patent.

Withdrawal of this rejection is respectfully requested.

E. Obviousness-Type Double Patenting Rejection Over U.S. 6,399,189

Claims 44-56 and 58 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-20 of U.S. Patent No. 6,399,139. Although the conflicting claims are not identical, the Examiner believes they are not patentably distinct from each other because both are drawn to food compositions to which cocoa polyphenols are added.

F. Applicants' Response To Obviousness-Type Double Patenting Rejection Over The '389 Patent

It is respectfully submitted that the food products claimed in the '139 patent and the present claims are not obvious variants of one another. The food product of the '139 patent is an

improved food product containing carbohydrate and/or milk ingredients and a cocoa ingredient where the cocoa polyphenols in the cocoa ingredient are conserved during processing of the cocoa-containing ingredient(s) (e.g., chocolate liquor, partially or fully defatted cocoa solids, cocoa extract, or synthetic procyanidins or derivatives thereof) into the food. The cocoa polyphenols are conserved by pretreating the carbohydrate and/or the milk ingredient(s) with an antioxidant, an emulsifier, a fat, and/or a flavorant before adding of the cocoa ingredient.

The only common feature of the claimed food products is the use of a cocoa extract which in the case of the '139 patent is added to the food after the carbohydrate and/or milk ingredient is pretreated with an antioxidant, an emulsifier, a fat, and/or a flavorant. The cocoa extract additive presently claimed can be added to the food at any time and any carbohydrate and/or milk ingredient present does not have to be pretreated with an antioxidant, an emulsifier, a fat, and/or a flavorant.

Withdrawal of this rejection is respectfully requested.

G. Provisional Obviousness-Type Double Patent Rejection Over Ser. No. 09/768,473

Claims 44-45 and 58 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of the copending '473 application. Although the conflicting claims are not identical, the Examiner believes they are not patentably distinct from each other because both are apparently drawn to food compositions comprising cocoa polyphenols. The Examiner notes that this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

H. Applicants' Response to Obviousness-Type Double Patenting Rejection
Over The '753 Application

Since the '753 application is allowed and the issue fee was paid, Applicants are responding to this rejection.

It is respectfully pointed out that the '753 application contains no food claims. All the claims are directed to a cocoa extract. A food containing a cocoa extract as an additive is not an obvious variant of the cocoa extract itself.

Withdrawal of this rejection is respectfully requested.

I. 35 U.S.C. §102(b) Rejections

Claims 44-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeigler et al. (CCB Rev. 1983), Omori (JP 08205818 – JPAB Abstract), Maruyama et al. (JP 04077424, Kattenberg (US 4,704,292), Helmona AG (FR 2307779-DWPI Abstract + French patent, Osakabe et al. I (JP-274894-English translation), or Osakabe et al. II (JP 7-213251 – English translation), with evidence provided by Hammerstone et al. (J. Agricult. Food Chem., 1999). The Examiner notes that Hammerstone et al., is not being cited as prior art, but instead as evidence to show that various prior art cocoa extracts inherently contain polyphenols such as those claimed.

The Examiner believes that each of the cited references teach food compositions to which cocoa polyphenols are added. According to the Examiner, Zeigler et al. teach the addition of epicatechin-containing cocoa extracts from which interfering xanthine alkaloids such as caffeine and theobromine have been removed as an antioxidant for various fat-containing foods such as edible vegetable oils, Omori teaches the addition of epicatechin or oligomers thereof to a health food, Maruyama et al. teach the addition of epicatechin as well as dimers and/or trimers thereof

to hard candy, Kattenberg teaches the addition of a cocoa powder extract containing monomeric and polymeric polyphenols such as catechin, dimeric procyanidines B1 to B5, trimeric procyanidin C1, and related compounds to various milk products, Helmona AG teaches the addition of catechin, and oligomers thereof to food as an antioxidant, and each of Osakabe et al. I and II teach the addition of cocoa extracts having antioxidant activity to food. The Examiner relies on the entire document of Hammerstone et al. including the figures as evidence that the cocoa products disclosed in the cited references would inherently comprise naturally occurring polyphenols such as epicatechin, catechin, and procyanidin oligomers.

The Examiner, concludes, each of the cited references anticipates the instant claims.

J. Applicants' Response to §102(b) Rejections

It is respectfully submitted the Examiner's rejection is improper. Despite his protestations to the contrary, the Examiner is treating the Hammerstone et al. article as if it were prior art. The Examiner has cited no MPEP section, or more importantly CAFC decision, supporting his position that the Patent Office can use the disclosure in a non-prior art publication to anticipate prior art compositions that are not disclosed therein.

The Hammerstone et al. article reports the extraction of polyphenols from fresh, freeze-dried cocoa beans which were ground, the ground cocoa mass was extracted with hexane to remove the lipids, and the lipid-free solids were air dried. The fat-free solids were then extracted twice with 70 vol. % acetone in water followed by two additional extraction with 70 vol. % methanol in water. The extracts were combined, and the solvent was removed. The aqueous extract was then freeze dried. The procyanidin composition of the freeze dried cocoa extract was then determined using a modified normal phase HPLC method. See the discussion "Extraction of Polyphenols from Cocoa and Chocolate" on p. 491. This is the extraction procedure disclosed

and claimed in U.S. 5,554,645 (the '645 patent). This application claims priority to the application which matured the '645 patent.

For Hammerstone et al. to be evidence that the cocoa products of Zieglader et al., Omori, Murayami et al., Kattenberg, Helmona A.G., and Osakabe et al. I and II anticipate the claimed cocoa extracts can only be persuasive if Hammerstone et al. analyzed and reported the composition of these cocoa products and confirmed the presence of catechin, epicatechin, and procyanidin oligomers in each of the prior art cocoa products. Hammerstone et al. did not do such analyses.

Anticipation requires the disclosure in a single piece of prior art of each and every limitation of the claimed invention. *Electro Med. Sys. S.A. v. CooperLife Sciences*, 34 F. 3d, 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). The Examiner has not met his burden of showing that the cited references meet every limitation of the claimed cocoa extract.

K. §102(b) Rejection Over Kashket

Claims 44 and 47-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kashket (U.S. 4,906,480).

According to the Examiner, Kashket teaches the addition of a polyphenol such as epicatechin to food. The Examiner concludes, therefore, that the reference anticipates the above claimed food.

In view of the amendment of Claim 44, and the claims directly or indirectly dependent thereon, to include the limitations of non-rejected Claim 45 (directed to catechin, epicatechin, and procyanidin oligomers thereof), it is believed the rejection of Claims 44 and 46-55 are overcome. Please note rejected Claim 56 was canceled.

L. §103(a) Rejections

Claims 44-56 and 58 are rejected under 35 U.S.C. 103(a) as being obvious over Zieglader et al., Omori, Maruyama et al., Kattenberg, Helmona AG, Osakabe et al. I, or Osakabe et al. II, and/or Kashket, and if necessary in view of Clapperton et al. (XVI Intl. Conf. Of Groupe Polyphenols, 1992), with evidence provided by the 1999 Hammerstone et al. article. The Examiner again notes that Hammerstone et al. is not being cited as prior art, but instead as evidence to show that various prior art cocoa extracts inherently contain polyphenols such as those claimed.

The primary references are relied upon for the reasons set forth above. Clapperton et al. is relied on for its teaching that xanthine alkaloids such as caffeine and theobromine are associated with the bitter astringent taste in cocoa.

The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to remove xanthine alkaloids from one or more of the reference cocoa extracts because Zieglader et al. teach that xanthine alkaloids such as caffeine and theobromine interfere with the antioxidant activity of cocoa polyphenols and, if necessary, because Clapperton et al. teach that xanthine alkaloids impart bitterness and astringency to cocoa products which would be undesirable when adding cocoa extracts to food.

In addition, the Examiner notes that, as evidenced by the analytical assays performed by Clapperton et al. on cocoa products, the cocoa and cocoa extracts discussed above would intrinsically contain catechins, epicatechin, and epicatechin/procyanidin oligomers such as those claimed.

The Examiner believes that based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing

the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

M. Applicants' Response to §103(a) Rejections

As discussed above, the Examiner's reliance on the Hammerstone et al. article, which is not prior art is improper. Even if its use was proper, it does not present a *prima facie* case of obviousness because it reports no analytical data showing that the cocoa products of the cited references contain the claimed cocoa polyphenols, i.e., catechin, epicatechin, and procyanidin oligomers thereof.

The reliance of the Examiner on Clapperton et al. does not cure the deficiency of his inappropriate reliance on Hammerstone et al. to evidence analytical data not contained therein.

N. Closing

Withdrawal of all the rejections and an early allowance is respectfully requested. No new matter is presented.

A marked up version of the amended claims is attached.

Respectfully submitted,

Date: February 5, 2003

Margaret B. Kelley
Margaret B. Kelley
Reg. No. 29, 181
Attorney for Applicant(s)
Telephone: (212) 878-3145

MAILING ADDRESS

Margaret B. Kelley, Esq.
CLIFFORD CHANCE US L.L.P.
200 Park Avenue
New York, NY 10166

MARKED-UP VERSION SHOWING CHANGES

44. (amended once) A food comprising, as a food additive, a mixture of cocoa [polyphenol] polyphenols, isolated from cocoa beans as a cocoa extract, which comprises catechin, epicatechin, and procyanidin oligomers thereof.

46. (amended once) The food of Claim 45, wherein the procyanidin oligomers [include] are selected from the group consisting of dimers through dodecamers.

48. (amended once) The food of Claim [50] 47, wherein certain cocoa procyanidin fractions are selected and then pooled.

49. (amended once) The food of Claim [51] 44, wherein the cocoa extract is prepared by a process comprising the steps of:

- [(a) freeze drying cocoa beans and pulp;
- (b) depulping the freeze-dried cocoa mass;
- (c) dehulling the freeze dried cocoa beans;
- (d) grinding the dehulled cocoa beans to a cocoa powder;]
- reducing the cocoa beans to a cocoa powder;
- defatting the cocoa powder; and
- [(e)] extracting the cocoa polyphenols from the cocoa powder.

59. (new) The food of Claim 49, wherein the process of reducing the cocoa beans to a cocoa powder comprises the steps of:

- freeze drying cocoa beans and pulp;
- depulping the freeze dried cocoa mass;
- dehulling the freeze dried cocoa beans; and
- grinding the dehulled cocoa beans.